JUN 2 2 2001

510(k) Summary

Introduction

This Summary of Safety and Effectiveness document is intended to comply with requirements of the SMDA and 21CFR§807.92. FDA may make this summary available to the public within 30 days following a finding of substantial equivalence.

510(k) Submitted by

Sandhill Scientific, Inc.
9150 Commerce Center Circle #500
Highlands Ranch, CO 80126

USA Contact Person

Linda L. Diederich, MT-ASCP
VP of Marketing & Customer Relations
Tel: 303-470-7020 / Fax: 303-470-2975

Date Prepared

June 15, 2001

Trade Name of Device

Sandhill UniTip Catheter Pressure Sensor

Common Name of Device

Catheter Pressure Transducer

Classification Name

System, Gastrointestinal Motility (Electrical)

510(k) Classification

Class II

Device Description and Intended Use

This device is intended for use in the measurement of physiological pressures in the biliary tract of the human digestive system for diagnostic purposes. In particular, it is intended to aid in determination of the intraluminal pressures within the pancreaticobiliary ductal system, and the Sphincter of Oddi, for purposes of evaluation and diagnosis of dysfunction related to muscle tonus and the coordination of contractions between muscle groups. Measurements may be made in conjunction with fluid sampling or injection.

Comparison to Predicate Devices

The device is equivalent in safety and performance to prior legally marketed devices. In particular it is equivalent to:

K792177 - Millar MIKRO-TIP Catheter Transducer, Manufactured by Millar Instruments, Inc., ECRP (Biliary or Sphincter of Oddi) Catheters only.

K900058 - Wilson-Cook Biliary Motility Catheter, Manufactured by Wilson-Cook Medical, Inc.

The Sandhill Catheter Pressure Transducer is equivalent in design and construction to the Millar device, but differs in that its indicated use is limited to biliary manometry. The Sandhill device is equivalent in indicated use to the Wilson-Cook device, but differs in design and construction in that it incorporates solid state catheter tip sensing elements.

Non-Clinical Testing

The requirements of the following standards have been used in part to establish substantial equivalence:

EN 1441 "Medical Devices – Risk Analysis"

EN 60601-1-2 "Medical Electrical Equipment – Part 1: General Requirements for Safety: Electromagnetic Compatibility – Requirements and Tests"

EN 30993-1 / ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing"

The company did not conduct, nor depend on, clinical studies in order to establish substantial equivalence.

Risk Management

This device has been designed to either completely eliminate or mitigate all known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous application of a risk management program. One or more of the following means (in order of preference) was used to implement mitigation of health hazards identified by the risk management program:

1. Design modifications.
2. Detection of hazard conditions and alerting of the user.
3. Identification of any potentially undetectable health hazard conditions in the instructions for use or other device labeling.

The user must be qualified in biliary diagnostic procedures, trained in the insertion and use of biliary catheters, and must be familiar with all labeling and instructions for use associated with the device. The company believes many device health hazards are due to user error and failure to follow instructions for use.

Sandhill Scientific believes that the Sandhill UniTip Catheter Pressure Sensor is safe and effective when used as instructed by knowledgeable and trained personnel, and performs as well as or better than the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2001

Linda L. Diederick, MT-ASCP
VP of Marketing & Customer Relations
Sandhill Scientific, Inc.
9150 Commerce Center Circle, #500
HIGHLANDS RANCH CO 80126

Re: K002427
Sandhill Solid State UniTip Biliary Catheter
SOL Model #S981300
Dated: May 25, 2001
Received: May 30, 2001
Regulatory Class: II
21 CFR §876.1725/Procode: 78 FFX

Dear Ms. Diederick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indications for Use

510(k) Number: K002427

Device Name: Sandhill Solid State Biliary Catheter

Indications for Use:

This device is intended for use in the measurement of physiological pressures in the biliary tract of the human digestive system for diagnostic purposes. In particular, it is intended to aid in determination of the intraluminal pressures within the pancreaticobiliary ductal system, and the Sphincter of Oddi, for purposes of evaluation and diagnosis of dysfunction related to muscle tonus and the coordination of contractions between muscle groups. Measurements may be made in conjunction with fluid sampling or injection.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

David G. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002427